

REMARKS/ARGUMENTS

Applicants and Applicants' attorney express appreciation to the Examiner for the courtesies extended during the recent interview held on October 28, 2003. Reconsideration and allowance for the above-identified application are now respectfully requested. Claims 41-85 are pending, wherein claims 1-15 and 17-40 have been cancelled and replaced with new claims 41-85.

I. NEW CLAIMS 41-85

New claims 41-85 have been added by this amendment to replace all previously pending claims. The new claims are based on the previously pending claims, but with modifications to overcome the rejections set forth in the Office Action. Because all the limitations contained in the new claims can be found in one or more of the previously pending claims, they are fully supported in the specification and do not introduce new matter.

New independent claim 41 claims a dental bleaching composition that comprises a peroxide bleaching agent, potassium nitrate, and a carrier, wherein the potassium nitrate has a concentration in a range of about 0.05% to about 1% by weight of the dental bleaching composition "so as to result in reduced tooth sensitivity that may be caused by said dental bleaching agent in the absence of said potassium nitrate when the dental bleaching composition is contacted with a person's teeth for a time sufficient to bleach teeth".

New independent claim 59 is similar to claim 41, but instead requires that the potassium nitrate is included "so as to result in reduced tooth sensitivity that may be caused by said dental bleaching agent in the absence of said potassium nitrate when the dental bleaching composition is passively maintained in contact with a person's teeth for at least about 15 minutes without brushing or scrubbing".

New independent claim 65 is similar to claim 41, but instead claims a dental bleaching composition that comprises potassium nitrate "in an amount of about 0.5% by weight of the dental bleaching composition".

Independent method claims 72, 77 and 81 recite the use of dental bleaching compositions as recited in claims 41, 59 and 65, respectively.

II. CLAIM REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

The Office Action rejects claims 21-25 and 30-35 under 35 U.S.C. § 112, first paragraph as not enabling a claim for preventing sensitivity. Accordingly, Applicants have removed the term "preventing" from the new claims as now presented.

III. CLAIM REJECTIONS UNDER 35 U.S.C. § 102

A. U.S. Patent No. 5,851,512

The Office Action rejects 1-15 and 17-40 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,851,512 to Fischer (hereinafter "Fischer '512"). As discussed during the Examiner Interview, Fischer '512 discloses desensitizing compositions that preferably include a desensitizing agent (*e.g.*, one or more of potassium nitrate, citric acid, citric acid salts, strontium chloride, etc.) in a range of about 0.1-10%, more preferably in a range of about 1-7%. Col. 8, lines 51-53 and 57-60. The desensitizing compositions of Fischer may optionally include other active agents, such as antimicrobial agents, anticariogenic agents, stabilizing agent, and bleaching agents. Col. 9, lines 1-42. Because Fischer is mainly directed to desensitizing compositions that do not include a bleaching agent, Fischer does not identify the optimal concentration (or concentration range) of potassium nitrate that works best in treating sensitivity that may be caused by the bleaching agent itself when contained within a desensitizing composition.

In the example section, Fischer explicitly teaches that increasing the concentration of potassium nitrate results in increased desensitization (or decreased tooth sensibility). Fischer teaches that compositions that include 5-10% potassium nitrate have "a high level of desensitizing activity" (Examples 5-7), while the compositions that included lesser amounts of potassium nitrate (Examples 1-4) were characterized as providing less desensitization. Indeed, the compositions of Examples 3 and 4, which included only 0.5% and 1% potassium nitrate, respectively, were characterized as "having reduced but significant desensitizing activity". Col. 13, lines 59-60; col. 14, lines 9-10 (emphasis added). In contrast, the compositions of Examples 5 and 6, which included 7% and 10% potassium nitrate, respectively, were characterized as having "a high level of desensitizing activity". Col. 14, lines 26 and 42. The composition of Example 7, which included 5% potassium nitrate, was characterized as having "a moderate to high level of desensitizing activity". Col. 14, lines 60-61. From the examples, the trend

according to Fischer is unmistakable—desensitizing activity increases as more and more potassium nitrate is added, with concentrations at the upper ends of the preferred ranges (*i.e.*, 7% and 10%) exhibiting the highest level of desensitization, while concentrations at or near the lower ends of the preferred ranges (*i.e.*, 0.5% and 1%) exhibiting the lowest level of desensitization from among the working examples.

Given the disclosure of Fischer, particularly the comparative levels of desensitization set forth in the examples, one of skill in the art would expect better tooth desensitization with increasing amounts of potassium nitrate. Indeed, this is likely the case where the dental composition is a dedicated desensitizing composition that includes no peroxide. However, as discovered by Applicants, increasing the concentration of potassium nitrate in a dental bleaching composition does not always result in better tooth desensitization. In fact, including a relatively low concentration of potassium nitrate (*i.e.*, from about 0.05-1%) was found to provide the best tooth desensitization, far better, in fact, than including 3% potassium nitrate. In a comparative study described at page 27, line 1 – page 29, line 4 of the specification, the inventors surprisingly found that including 3% potassium nitrate together with a peroxide bleaching agent did reduce tooth sensitivity at all but actually resulted in more tooth sensitivity compared to a bleaching composition that included no potassium nitrate. See also Fischer Declaration and Exhibit A filed together with Preliminary Amendment "A" on June 25, 2001 (a copy of which is included herewith as a courtesy to the Examiner). Because potassium nitrate is a well-known desensitizing agent, it was counterintuitive, as well as entirely contrary to the conventional wisdom, to discover that including a relatively small amount of potassium nitrate within an optimal range (*i.e.*, 0.05-1%) results in far better tooth desensitization than including more (*i.e.*, 3%) potassium nitrate.

As set forth in the MPEP § 716.02(a), the Federal Circuit held that discovering a result that is contrary to what is expected is strong evidence that the discovery is patentable:

"A greater than expected result is an evidentiary factor pertinent to the legal conclusion of obviousness . . . of the claims at issue." *In re Corkill*, 711 F.2d 1496, 226 USPQ 1004 (Fed. Cir. 1985). In *Corkill*, the claimed combination showed an additive result when a diminished result would have been expected. This result was persuasive of nonobviousness even though the result was equal to that of one component alone.

In the present invention, it was discovered that including less potassium nitrate (*i.e.*, 0.05-1%) actually resulted in far better tooth desensitization than including more potassium nitrate (*i.e.*, 3% potassium nitrate and, by extension, 3-10% potassium nitrate, which covers 70% of the preferred range disclosed in Fischer).

In short, whereas Fischer describes dental compositions that provide increasing tooth desensitization with increasing concentrations of potassium nitrate within the disclosed ranges of about 0.1-10% and about 1-7%, and whereas Fischer discloses the optional use of a peroxide dental bleaching agent in such dental compositions, Fischer does not teach or suggest the specific range (*i.e.*, 0.05-1%) where potassium nitrate was found to provide optimal tooth desensitization when used in combination with a peroxide bleaching agent. In fact, according to the comparative study, the desensitizing compositions that Fischer identifies as providing the best tooth desensitization in the absence of a peroxide bleaching agent (*i.e.*, that include 5-10% potassium nitrate) would likely not desensitize teeth at all, but would cause increased tooth sensitivity, if modified to include a peroxide bleaching agent. This is entirely contrary to what would have been expected given the state of the art at the time of the present invention. For this reason, the counterintuitive result of the present invention is strong evidence of nonobviousness according to *In re Corkill*.

With respect to anticipation, Fischer does not anticipate the claims of the present application because the desensitizing compositions according to Fischer do not inherently cause desensitization of teeth when modified to include a peroxide bleaching agent. Indeed, according to the comparative study, including 3% potassium nitrate together with a peroxide bleaching agent causes more sensitivity, and is therefore worse, than including no potassium nitrate at all. By extension, including even more potassium nitrate (*i.e.*, 3-10%) would be as bad, or worse, than including 3%. That means that at least 70% of all hypothetical dental bleaching compositions according to Fischer that include a peroxide bleaching agent and potassium nitrate would not result in decreased sensitivity, as required by every independent claim of the present application. Accordingly, it simply does not follow that dental compositions of Fischer that include both potassium nitrate and a peroxide bleaching agent inherently possess the characteristics of the compositions defined by claims 41-85 of the present application. For this reason, Fischer does not anticipate claims 41-85, either literally or inherently. And for the

reasons given above, claims 41-85 are nonobvious over Fischer, particularly in light of *In re Corkill*.

In the case where there is an overlap between a large range in the prior art and a narrow range in the claimed invention, MPEP § 2144.05 (I. Overlap of Ranges) states the following:

"A prior art reference that discloses a range encompassing a somewhat narrower claimed range is sufficient to establish a prima facie case of obviousness." [citation omitted.] However, if the reference's disclosed range is so broad as to encompass a very large number of possible distinct compositions, this might present a situation analogous to the obviousness of a species when the prior art broadly discloses a genus. [citations omitted.]

In the present situation, Fischer discloses a broad genus that includes many species of compositions having very different properties, three of which are as follows: (1) desensitizing compositions that include no peroxide and that desensitize at any concentration of potassium nitrate, with increasing concentrations of potassium nitrate resulting in better desensitizing activity; (2) dental compositions that include potassium nitrate and a peroxide bleaching agent in which the potassium nitrate does not provide any tooth desensitization; and (3) dental compositions that include potassium nitrate and a peroxide bleaching agent in which the potassium nitrate does provide tooth desensitization. The difference between the properties of species (2) and (3) is not one of degree, but of kind. In species (2), potassium nitrate desensitizes teeth in combination with a peroxide bleaching agent. In species (3), potassium nitrate does not desensitize teeth in combination with a peroxide bleaching agent. The problem with Fischer is that it does not describe how to distinguish between species (2) and (3). For this reason, one of skill in the art would not know how to obtain the bleaching compositions recited in claims 41-85 of the present application, which fall within species (2), rather than bleaching compositions that fall within species (3) following the teachings of Fischer and the state of the art at the time of the invention. Since species (2) is different from species (3) as a matter of kind, rather than degree, species (2) is a nonobvious species of the broad genus disclosed in Fischer. For this additional reason, claims 41-85 are nonobvious over Fischer.

In view of the foregoing, Applicants believe that claims 41-85 are neither anticipated by, nor obvious over Fischer.

B. U.S. Patent No. 5,985,249

The Office Action rejects 1-15 and 17-40 under 35 U.S.C. § 102(a) as being anticipated by U.S. Patent No. 5,985,249 to Fischer (hereinafter "Fischer '249"). Fischer '249 is generally directed to sticky dental compositions that may include one or more of a variety of active agents, including bleaching agents, desensitizing agents, antimicrobial agents, and anticariogenic agents. Fischer '249 does not explicitly disclose dental compositions that include any particular combination of active agents. Indeed, Examples 1-8 include potassium nitrate but no bleaching agent, while Examples 9-16 include a bleaching agent but no potassium nitrate. Whereas Fischer '249 discloses a broad genus that includes many possible species, the species defined by claims 41-85 of the present application are not specifically called out or identified. Thus, for substantially the same reasons given above with respect to Fischer '512, claims 41-85 are neither anticipated by nor obvious over Fischer '249. Moreover, because Fischer '249 is even more general than Fischer '512, the genus of possible compositions disclosed in Fischer '249 is much broader than the genus disclosed in Fischer '512. For this reason, claims 41-85 define an even more specific species compared to the broader genus of Fischer '249.

IV. DOUBLE PATENT REJECTIONS

The Office Action rejects various claims under the judicially created doctrine of obviousness double patenting as being obvious over claims 1-12, 15 and 16 of Fischer '512 and claims 1-10, 13 and 14 of Fischer '249. In response, Applicants have reviewed each of the foregoing claims and can find no teaching or suggestion for the specific narrow species of bleaching composition recited in claims 41-85. In particular, the claims in Fischer '512 and Fischer '249 are either directed to the broad genus described above or a patentably distinct species, neither of which render any of claims 41-85 "obvious" for purposes of obviousness-type double patenting.

As described above, disclosing and claiming a broad genus does not necessarily render a particular species obvious. Moreover, to the extent that a later-claimed species is shown to provide unexpected results relative to an earlier disclosed genus, the later-claimed species is a nonobvious variation of the earlier disclosed genus. Thus, for the same reasons given above for why claims 41-85 are nonobvious over the disclosures of the Fischer '512 and '249 patents, claims 41-85 are likewise nonobvious over the claims of the Fischer '512 and '249 patents.

Because the Fischer '512 and '249 patents neither teach nor suggest the specific range (*i.e.*, about 0.05-1%) or concentration (about 0.5%) for potassium nitrate recited in claims 41-85, they provide no written description support for such claims. Nor do they suggest any such range or concentration. It therefore follows that claims 41-85 are not attempting to claim the same invention, or an obvious variation of the invention, recited in any claim of either Fischer '512 or Fischer '249. For this reason, Applicants respectfully request reconsideration and withdrawal of the foregoing double patenting rejection.

The Office Action also rejects various claims under the judicially created doctrine of obviousness double patenting as being obvious over claims 1-7 and 10-20 of U.S. Patent No. 6,368,576 to Jensen et al.; claims 1-8, 10, 11, 13-19 and 23-26 of U.S. Patent No. 6,309,625 to Jensen et al.; and claims 1-23 of U.S. Patent No. 6,306,370 to Jensen et al. (together "Jensen patents"). In general, the Jensen patents are similar to Fischer '512 and Fischer '249, except that they disclose even higher concentrations of potassium nitrate (*i.e.*, up to 50% potassium nitrate). Accordingly, the Jensen patents disclose and claim an even broader genus of compositions than Fischer '512 and Fischer '249. Applicants have reviewed each of the claims of the Jensen patents and can find no teaching or suggestion for the specific narrow species of bleaching composition recited in claims 41-85. Like Fischer '512 and Fischer '249, the Jensen patent claims are either directed to a very broad genus or a patentably distinct species, neither of which render any of claims 41-85 "obvious" for purposes of obviousness-type double patenting.

As described above, disclosing and claiming a broad genus does not necessarily render a particular species obvious. Moreover, to the extent that a later-claimed species is shown to provide unexpected results relative to an earlier disclosed genus, the later-claimed species is a nonobvious variation of the earlier disclosed genus. Thus, for the same reasons given above for why claims 41-85 are nonobvious over the disclosures and claims of the Fischer '512 and '249 patents, claims 41-85 are likewise nonobvious over the disclosures and claims of the Jensen patents. Because the Jensen patents neither teach nor suggest the specific range (*i.e.*, about 0.05-1%) or concentration (about 0.5%) for potassium nitrate recited in claims 41-85, they provide no written description support for such claims. Nor do they suggest any such range or concentration. It therefore follows that claims 41-85 are not attempting to claim the same invention, or an obvious variation of the invention, recited in any claim of the Jensen patents.

For this reason, Applicants respectfully request reconsideration and withdrawal of this additional double patenting rejection.

V. **CONCLUSION**

In view of the foregoing, Applicants submit that claims 41-85 are in allowable form. In the event that the Examiner finds remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview, the Examiner is requested to contact the undersigned attorney.

Dated this 3rd day of November 2003.

Respectfully submitted,



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